10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, RINVOQ (upadacitinib) indicated for the treatment of adults with moderately to severely active rheumatoid arthritis who have had an inadequate response or intolerance to methotrexate. Subsequent to this approval, the USPTO received a patent term restoration application for RINVOQ (U.S. Patent Nos. 8,962,629; RE47221) from AbbVie and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated April 5, 2021, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of RINVOQ represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for RINVOQ is 2,604 days. Of this time, 2,365 days occurred during the testing phase of the regulatory review period, while 239 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* July 1, 2012. FDA has verified the applicant's claim that the date the investigational new drug application became effective was on July 1, 2012.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* December 21, 2018. FDA has verified the applicant's claim that new drug application (NDA) for RINVOQ (NDA 211675) was initially submitted on December 21, 2018.

3. *The date the application was approved:* August 16, 2019. FDA has verified the applicant's claim that NDA 211675 was approved on August 16, 2019.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 939 days or 989 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: June 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14431 Filed 7–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2018–N–3728]

Agency Information Collection Activities; Proposed Collection; Comment Request; Collection of Conflict-of-Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on collection of conflict-of-interest information for participation in FDA employee fellowship and traineeship programs.

DATES: Submit either electronic or written comments on the collection of information by September 6, 2022.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 6, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of September 6, 2022. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2018–N–3728 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Collection of Conflict-of-Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *PRAStaff@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Collection of Conflict-of-Interest Information for Participation in Food and Drug Administration Non-Employee Fellowship and Traineeship Programs

OMB Control Number 0910–0882—Extension

Section 742 (b) of the Food, Drug and Cosmetic Act (21 U.S.C. 379l) allows FDA to conduct and support intramural training programs through fellowship and traineeship programs. Prospective participants in these programs must complete financial disclosure forms to determine if there is a conflict of interest that would preclude participation. These new forms provide the FDA with information about financial investments and relationships from non-employee scientists who participate in FDA fellowship and traineeship programs. Participants in FDA fellowship and traineeship programs will be asked for certain information about financial interests and current relationships: (1) description of the financial interest; (2) the type of financial interest (*e.g.,* stocks, bonds, stock options); (3) if the financial interest is an employee benefit from prior employment; (4) value of financial interest; (5) who owns the financial interest (*e.g.,* self, spouse, minor children); (6) employment relationship with an FDA significantly regulated organization (SRO); and (7) service as a consultant to an FDA SRO, and/or proprietary interest(s) in one of more product(s) regulated by FDA, including a patent, trademark,

copyright, or licensing agreement. The purpose of the financial information is for FDA to determine if there is a conflict of interest between the Fellow's or Trainee's financial and relationship interests and their activities at FDA. The collection of information is mandatory to participate in FDA's fellowship and traineeship programs.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Oak Ridge Institute for Science and Education Fellowship	500	500	500	1	500
Traineeship Program	500	500	500	1	500
Reagan Udall Fellowship at FDA	50	50	50	1	50
Total					1050

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of the information collection since our last request for OMB approval, we have made no adjustments to our burden estimate.

Dated: June 30, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2022–14439 Filed 7–6–22; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2021–N–1358]

Jhanna Novikov: Final Debarment Order

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is issuing an order under the Federal Food, Drug, and Cosmetic Act (FD&C Act) debarring Jhanna Novikov for a period of 5 years from importing or offering for import any drug into the United States. FDA bases this order on a finding that Ms. Novikov was convicted of one felony count under Federal law for smuggling goods into the United States. The factual basis supporting Ms. Novikov's conviction, as described below, is conduct relating to the importation into the United States of a drug or controlled substance. Ms. Novikov was given notice of the proposed debarment and was given an opportunity to request a hearing to show why she should not be debarred. As of April 8, 2022 (30 days after receipt of the notice), Ms. Novikov had not responded. Ms. Novikov's failure to respond and request a hearing within the prescribed timeframe constitutes a waiver of her right to a hearing concerning this matter.

DATES: This order is applicable July 7, 2022.

ADDRESSES: Submit applications for termination of debarment to the Dockets Management Staff, Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, or at *https://www.regulations.gov.*

FOR FURTHER INFORMATION CONTACT: Jaime Espinosa, Division of Enforcement (ELEM–4029), Office of Strategic Planning and Operational Policy, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857, 240–402–8743, or at *debarments@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

Section 306(b)(1)(D) of the FD&C Act (21 U.S.C. 335a(b)(1)(D)) permits debarment of an individual from importing or offering for import any drug into the United States if the FDA finds, as required by section 306(b)(3)(C) of the FD&C Act, that the individual has been convicted of a felony for conduct relating to the importation into the United States of any drug or controlled substance.

On December 9, 2021, Ms. Novikov was convicted, as defined in section 306(l)(1) of FD&C Act, in the U.S. District Court for the Southern District of Florida-West Palm Beach Division, when the court accepted her guilty plea and entered judgment against her for the offense of smuggling goods into the United States, in violation of 18 U.S.C. 545. FDA's finding that debarment is appropriate is based on the felony conviction referenced herein. The factual basis for this conviction is as follows: As contained in the indictment, filed on July 28, 2021, and the plea agreement, filed on September 30, 2021, both from Ms. Novikov's case, on July 25, 2018, Ms. Novikov agreed to treat the facial wrinkles of an individual who was an undercover investigator with the Florida Department of Health with ''fillers'' for $600 and ''BOTOX'' for $300. BOTOX, or botulinum neurotoxin Type A, is the most well-known neurotoxin approved by FDA to treat facial wrinkles. On August 10, 2018, the investigator returned to Ms. Novikov's residence for her ''BOTOX'' treatment, and as Ms. Novikov made preparations and drew a liquid into a syringe, agents from FDA's Office of Criminal Investigations (OCI) entered and took control of her residence. After obtaining a warrant, OCI agents searched Ms. Novikov's home. Agents seized various vials of white powder from Ms. Novikov's residence, including two labeled ''NEUROXIN Botulinum Toxin Type A,'' 14 labeled ''CASPIS,'' and one with no label. Analysis by the FDA Forensic Chemistry Center determined that the two Neuroxin vials, a sample of four of the Caspis vials, and the unlabeled vial all contained botulinum toxin, the active ingredient in BOTOX; however, a search of FDA records revealed that these drugs had not been approved by FDA and were unapproved new drugs as well as misbranded drugs. Agents did not find any BOTOX or other FDA-approved drugs containing botulinum toxin in Ms. Novikov's home. A subsequent forensic examination of Ms. Novikov's cell phone, which had been seized by OCI agents, revealed that she had imported these unapproved new drugs from Mexico, in violation of the FD&C Act, and Ms. Novikov had been importing such drugs since 2016.

As a result of this conviction, FDA sent Ms. Novikov, by certified mail, on March 1, 2022, a notice proposing to debar her for a 5-year period from importing or offering for import any drug into the United States. The proposal was based on a finding under section 306(b)(3)(C) of the FD&C Act that Ms. Novikov's felony conviction under Federal law for smuggling goods into the United States, in violation of 18